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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,844	07/10/2003	Johann Kindlein	3560-0131P	9987

2292 7590 06/13/2007

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EXAMINER	
HOPKINS, CHRISTINE D	
ART UNIT	**PAPER NUMBER**
3735	

NOTIFICATION DATE	DELIVERY MODE
06/13/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/615,844	KINDLEIN ET AL.	
	Examiner	Art Unit	
	Christine D. Hopkins	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 April 2007 has been entered. The Examiner acknowledges the amendment to claim 1. Claims 1-22 are pending.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d), filed 31 May 2007. The certified copy of Application No. 02077799.1, has been filed.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. With regards to the "means for delivering...radiation energy" in claims 1, 8, 9, 10, this limitation meets the three-prong test per MPEP 2181 and thereby invokes 35 USC 112 6th paragraph.

3. Regarding claims 5 and 19, which recite a "catheter probe drive means for", claim 6 which recites "a catheter tube drive means for" and claim 10 which recites a "wire drive means for"; the examiner does not consider these claims to invoke 35 USC 112 6th paragraph. The "catheter probe drive means", "catheter tube drive means" and the "wire drive means" are all phrases referring to elements and therefore the word "means" has been used to indicate an apparatus.

4. **Claims 1, 2, 3, 4, 6, 7, 11 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (U.S. Patent No. 5536240) in view of Singh (U.S. Patent No. 6599237 B1).

5. Claim 1 - Edwards at al. teaches a catheter probe (182), having an elongated body with a circumferential surface, a distal end (186) and a proximal end (182), said elongated body of said catheter probe (184) (figure 13) having a longitudinal bore extending from said distal end towards at least one outlet opening (216) (figure 6) present in said circumferential surface near said proximal end (column 7, lines 19 – 29); a catheter tube (54) (figure 4) having a distal end and a proximal sharp end (56)(figure 5)(column 7, lines 29-30), which catheter tube is to be inserted with its proximal sharp end through said longitudinal bore of said elongated body, said outlet opening and through said urethral wall towards at least one desired location within the prostate to be treated (column 20, lines 39-52). Edwards et al. teaches a catheter probe as described above but does not teach the use of a urethral probe made of a material to be perforated.

6. Singh teaches a urethral probe (10) (figure 2, 2A) of sufficient size to accommodate other surgical instruments (column 2, lines 30-32). This sheath, as disclosed by Singh, "acts like an artificial protective lining for the body opening through which it is passed, e.g., the urethra" (Abstract). It is noted that the urethral probe is made of rubber (column 3, lines 63-67), as suggested by the instant specification, as the material to be perforated. The rubber material allows the urethral probe to be "perforated" in the sense that it splits as an oversized instrument is placed within it (column 6, lines 26-38). Furthermore, instruments including a catheter probe "can be inserted and removed by being passed into the body through the lumen of the sheath" (Abstract) and are thus movably accommodated within the urethral probe.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a urethral probe composed of a material capable of being perforated as taught by Singh with a catheter probe of Edwards et al. to allow quick and more accurate positioning of a therapy delivering catheter while minimizing the discomfort to the patient (Singh column 3, lines 50-51).

7. Claim 2 – The combination as described above teaches a urethral probe that allows multiple insertions, removals and manipulations of various surgical instruments (column 2, lines 6-8).

8. Claim 3 – Singh teaches a urethral probe as described above as an elongated self-supporting tube (10) with a proximal end (16) and distal end (14) and a longitudinal lumen (18) (figures 2, 2A) to be introduced transurethrally into the body of the patient (claim 6).

9. Claim 4 – Singh teaches a urethral probe as described above having an elongated tubular body (10) with a central longitudinal lumen (18) (figure 2) of sufficient size to accommodate elongated surgical devices (claim 1) (column 12, lines 66-67; column 13, line 1).

10. Claim 6 – Edwards et al. teaches a catheter tube drive means for moving said catheter tube within said catheter probe by using control tabs (192 and 194) located on the handle portion (180) of the device (figure 13)(column 13, lines 41-44).

11. Claim 7 – Edwards discloses a flexible catheter tube (54)(column 9, lines 44-45) having a sharpened end (56)(figure 4) (column 7, lines 28-30).

12. Claims 11 and 12 – the urethral probe of Singh can be either a resilient, highly flexible material or a stiffer material (column 3, lines 64-67; column 4, lines 1-2).

13. The combination of Edwards et al. and Singh as described above is obvious over claims 1, 2, 3, 4, 7, 11 and 12 and complies with the invocation of 35 USC 112 6th paragraph as it shows an equivalent "means for delivering" since it performs the same function of delivering treatment to specific tissues within a body.

14. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Edwards et al. and Singh as applied to claim 1 above, and further in view of Shiber (U.S. Patent No. 5135531). The combination of Edwards et al. and Singh teaches a flexible catheter but does not disclose a catheter probe drive means for its placement and adjustment.

15. Claim 5 – the flexible catheter of Shiber can be advanced and rotated (column 3, lines 64-65) using a drive means (column 4, lines 40-46).

16. In views of the teachings of Shiber, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a drive means to position and reposition a catheter or tube, as described by the combination of Edwards et al. and Singh above, to reduce human error and increase the accuracy of positioning the device within the patient when compared to traditional manual methods as the drive means can be controlled by a computer or electronic device.

17. **Claims 8-10, 18 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Edwards et al. and Singh as applied to claims 1 and 7, and further in view of Kindlein et al. (U.S. Patent 6454696 B1). The combination of Edwards et al. and Singh teaches the use of a catheter delivery device to deliver treatment to a particular location within the body but does not disclose a wire means to load the catheter delivery device and drive the treatment through the catheter into the tissue.

18. Claim 8 - Kindlein et al. (U.S. Patent 6454696 B1) teaches a delivery method comprising at least one wire (132)(figure 12) having a distal end (column 5, lines 12-14) and a proximal end; and at least one energy emitting source (claim 1) to be inserted by means of said proximal end of said wire through said catheter tube (10)(figure 1) towards said location to be treated (column 5, lines 19-21).

19. Claim 9 – the apparatus of Kindlein et al. (U.S. Patent 6454696 B1) as described above comprises a means for inserting said energy source within the catheter tube (claim 19).

20. Claim 10 – Kindlein et al. (U.S. Patent 6454696 B1) teaches a means for delivering comprising a wire drive means for moving a wire together with an energy-emitting source through a catheter (claims 1 and 20).

21. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the catheter delivery device of the combination of Edwards et al. and Singh, with a wire drive means to deliver an energy source, in view of the teachings of Kindlein et al. (U.S. Patent 6454696 B1) to eliminate the many specialized and delicate tasks involved with performing this method manually, and to increase the accuracy in the placement of the treatment (column 1, lines 30-34).

22. Furthermore, the combination of Edwards et al. and Singh as described above does not disclose a method using a computer and treatment plan by which the delivery device is controlled.

23. Claim 18 – Kindlein et al. (U.S. Patent 6454696 B1) teaches that the location within the tissue to be treated is monitored and controlled by a computer program (column 1, lines 38-40) according to planning information delivered by imaging means (7)(figure 1)(column 2, lines 43-49).

24. Claim 19 – Kindlein et al. (U.S. Patent 6454696 B1) teaches a control means (12)(figure 1)(column 4, lines 25-30) for delivering treatment to the tissue comprising

imaging means (7)(figure 1)(column 2, lines 43-49) and at least one computer planning treatment system (12a)(figure 1)(column 1, lines 38-40).

25. It would have been obvious to one having ordinary skill in the art at the time the invention was made to control the device as described above, in view of the teachings of Kindlein et al. (U.S. Patent 6454696 B1), using a computer program in combination with a treatment plan to administer treatment to a patient because it eliminates human error and increases efficiency (column 1, lines 30-34).

26. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Edwards et al. (U.S. Patent No. 5536240) and Jagpal (U.S. Patent No. 5257979) and further in view Webster (U.S. Patent No. 5569220).

27. Edwards at al. teaches a catheter probe (182), having an elongated body with a circumferential surface, a distal end (186) and a proximal end (182), said elongated body of said catheter probe (184) (figure 13) having a longitudinal bore extending from said distal end towards at least one outlet opening (216) (figure 6) present in said circumferential surface near said proximal end (column 7, lines 19 – 29); a catheter tube (54) (figure 4) having a distal end and a proximal sharp end (56)(figure 5)(column 7, lines 29-30), which catheter tube is to be inserted with its proximal sharp end through said longitudinal bore of said elongated body, said outlet opening and through said urethral wall towards at least one desired location within the prostate to be treated (column 20, lines 39-52). Edwards et al. teaches a catheter probe as described above but does not teach the use of a urethral probe.

28. Jagpal teaches a urethral probe (70)(figure 5)(column 12, lines 16-17) with a lumen (76) through which a catheter probe is movable accommodated within (column 10, lines 17-21).

29. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the urethral probe of Jagpal with the catheter device of Edwards et al. to allow repositioning of a catheter (column 5, lines 33-34), to reduce risk to the patient (column 12, lines 22-23). While Jagpal teaches a urethral probe through which devices may be inserted to treat tissues within the body, it does not disclose the nature of the material from which the urethral probe is made.

30. Claim 13 – Webster (U.S. Patent No. 5569220) teaches the use of a flexible catheter with reinforced mesh (column 2, lines 7-10). Merriam-Webster Online Dictionary teaches the term "grating" to mean a partition or covering of parallel or crossed bars. Compact's Oxford Dictionary defines "mesh" as material made of a network of wire or thread. Therefore the examiner is taking the term mesh to mean a grating of a plurality of filaments.

31. It would have been obvious to one of ordinary skill in the art at the time the invention was made to reinforce the sheath of Jagpal for use with the delivery catheter of Edwards et al., as described above, with the mesh of Webster (U.S. Patent No. 5569220) to provide high torsional stiffness with increased flexibility (column 1, lines 56-58). This combination improves the control over placement of the device within the body (column 1, line 56) and provides tissue protection while increasing the ease of manipulation of devices within the lumen.

32. **Claims 14, 15, 16 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Edwards et al., Japgal and Webster as applied to claim 13 above, and further in view of Tiller et al. (PGPUB US 2003/0091641 A1).

33. The delivery device as taught by the combination of Edwards et al., Japgal and Webster includes a delivery catheter comprising a catheter probe, a urethral probe and a sheath made of a grating of a plurality of filaments but does not disclose specific types of materials or coatings.

34. Tiller et al. teaches that medical devices can be made of and coated with a variety of materials, including metals, polymers and bioabsorbable materials. Medical devices, including urinary catheters, are prone to biofilm formation on their surfaces ([0181]).

35. Claim 14 - Tiller et al. teaches that medical devices can be made of polymers ([0060]) and materials considered to be bioabsorbable ([0162]).

36. Claim 15 – Tiller et al. teaches that medical devices can be made of metals ([0060]).

37. Claim 16 - Tiller et al. teaches coating of medical devices with tissue friendly coatings including polymers ([0052]).

38. Claim 17 – Tiller et al. teaches coating of medical devices with polyurethanes ([0052]).

39. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device as described by Edwards et al., Singh

and Japgal in view of the teachings of Tiller et al., using metal, polymers and/or a bioabsorbable material as these are common materials used in the art as well as materials which are able to be sterilized, therefore minimizing tissue damage and lowering the risk of infection ([0003]).

40. **Claims 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Edwards et al. and Singh as applied to claim 1 above, and further in view of Bradshaw et al. (U.S. Patent No. 5139473). The device taught by the combination of Edwards et al. and Singh includes a catheter delivery device and a sheath but does not disclose the use of a computer or electronic system to deliver treatment to the patient.

41. Claim 20 – Bradshaw et al. teaches the use of a radioactive energy sources in common medical procedure using guide tubes, including catheters, and wire drive means (column 17, claim 1).

42. Claim 21 – the energy sources of Bradshaw et al. are high dose rate sources (column 1, lines 38 –47).

43. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device as described above by the combination of Edwards et al. and Singh, in view of the teachings of Bradshaw et al., to administer a treatment using a high dose rate source and to control the delivery via a computer. Bradshaw discloses that other radiation treatments have disadvantages including "long residency times and the requirement for surgical implantation and removal, the latter

with its attendant trauma to adjacent normal tissue" (column 1, lines 34-36). In comparison, Bradshaw states that the "significant offsetting advantage of (using high dose rate sources as) a treatment regime is its extreme speed" taking "only a few minutes" and "the patient carries no radioactive implants within him from the treatment center" (column 1, lines 44-47). When using high dose rate sources, it "cannot be openly handled or exposed to treatment facility doctors and personnel" and "even relatively short exposures may result in radiation burns" therefore it "must be conducted remotely" (column 1, lines 48-52). With respect to radiation treatments other than seed implantation, the method of Bradshaw is a functional equivalent because it ablates the targeted tissue while leaving the surrounding tissue in tact.

44. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Edwards et al. and Singh as applied to claim 1 above, and further in view of Hung et al. (U.S. Patent No. 6391026 B1). The device taught by the combination of Edwards et al. and Singh includes a catheter delivery device and a sheath but does not disclose the use of an antenna as an energy emitting source to emit radiowaves.

45. Claim 22 – Hung et al. teaches a method using an energy emitting source (409) including an antenna (410) (column 7, lines 9-12, lines 24-26) emitting radiowaves (column 13, lines 44-46)(figure 8c).

46. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the catheter device as described by the combination of Edwards et al. and Singh above with the radiowave emitting antenna of Hung et al. because this is a controllable method of ablating tissue within the body while leaving

other tissue in tact (column 5, lines 3-6). Hung discloses that "other energy forms could also be used, such as light, ultrasound, radiation, microwave energy, heat, cold, direct current, and the like" (Abstract). Therefore the method of Hung is functionally equivalent.

Response to Arguments

47. Applicant's arguments filed 9 April 2007 with respect to the rejection of claims 1-4, 6-7, and 11-12 under 35 U.S.C. 103(a) citing Edwards et al. ('240) in view of Singh ('237) have been fully considered and are not persuasive. Applicant contends that Singh does not suggest the insertion of a medical tool such as radioactive seeds through the circumferential wall of the urethral probe and the urethral wall until it is within the tissue of the prostate gland and that Singh only teaches a urethral probe which facilitates the insertion of another tube. However, this argument is not persuasive. The sheath or "urethral probe" of Singh is perforated (causing the insertion of a medical tool through the circumferential wall of the urethral probe) when an oversized instrument is inserted into the urethral probe (column 6, lines 26-38). Such a perforation is facilitated by the rubber material from which the "urethral probe" is composed, as discussed in the rejection supra. In this particular case, the "oversized instrument" is determined to be the catheter tube having a sharp end as taught by Edwards. It is further noted that the reference to Singh satisfies the requirement of a "urethral probe" and falls within the bounds of analogous art since it also teaches the transurethral insertion of a medical instrument that reduces discomfort to the patient

(column 2, lines 61-66 and column 6, lines 15-22). Thus, it is submitted that the combination of Edwards and Singh teach a urethral probe made of a material to be perforated by a catheter tube. In view of the foregoing, the Applicant has failed to structurally distinguish the invention from the prior art references and therefore the rejections regarding claims 1-22 in the Office Action dated 8 January 2007 are upheld.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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